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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,315	07/21/2003	Duane D. Blatter	11502/26:1 US	7286
7590	09/20/2005		EXAMINER	
Kevin B. Laurence STOEL RIVES LLP One Utah Center 201 South Main Street, Suite 1100 Salt Lake City, UT 84111			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 09/20/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,315	BLATTER, DUANE D.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 July 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/6/03</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 8, 12, 17 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21, 24 of U.S. Patent No. 6,595,941 to Blatter. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a broader embodiment of the patented invention. Specifically, the patented invention includes the steps of providing occludable extraction and delivery tubes, anastomosing one end of the tubes to a blood vessel, occluding the access tubes, opening the access tubes, sending blood to a treatment device, and reoccluding the access tubes when the treatment is completed.

3. Claims 9, 10, 11, 13, 18, 22-29, 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 19, 23, 24, 53 of U.S. Patent No. US 6,656,151 to Blatter. Although the conflicting claims

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are not identical, they are not patentably distinct from each other because they claim the same general structure of an access tube anastomosed to a blood vessel with a selectively operable occluder therein, along with the other limitations of the instantly presented claims. With regard to the shape of the balloon, the '151 patent fails to claim the shape of the balloon, but absent a showing of criticality of the shape, such a recitation of the shape is held to be a matter of obvious design choice.

4. Claims 14-16, 19, 20, 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 of U.S. Patent No. US 6,663,590 to Blatter. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an access tube with a selective occluder with a physiologically active agent disposed on the occluder. Further, the '590 patent claims a graft vessel means with an anastomosis end and a port end. That port end, as illustrated by the drawings (see FIG 7A), serves to close the end of the access tube opposite the anastomosis end. Similarly, the graft vessel means is adapted to anastomose a vessel at its anastomosis end. The illustrated graft vessel (see, again FIG 7A) has anastomosis components, including an anastomosis ring. Therefore, the instant invention is unpatentable over the '590 patent. Since the instantly claimed method recites only the steps of providing the previously patented structure, the recitation of said structure renders the steps of supplying said structure obvious.

5. Claims 6, 7, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1 of U.S. Patent

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No. 6,595,941 to Blatter in view of US 4,421,507 to Bokros. Blatter discloses the method and device as claimed with the exception of placing the access device in a percutaneous position. Bokros discloses a percutaneous access port with a plug that allows patients to self-administer medications and treatments directly to his or her own vascular system without repeatedly puncturing the skin, which may lead to infection and scarring. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to place the access device disclosed by Blatter in a percutaneous position with a plug in order to allow patient access with minimal scarring and infection, as taught by Bokros.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 8-10, 15, 18, 19, 22, 23, 25, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,822,341 to Colone. Colone discloses a vascular access fistula with access tubes 36, 38, and corresponding port holes that may be anastomosed with sutures to the sidewalls of vessels 68 and 70, providing fluid communication. The access tubes are occluded by valve 22 that may be opened and closed by moving the occluding valve to establish and halt flow through the tubes to a

blood treatment machine. The occluding valve is in a closed position by default, creating a self-sealing port in fluid communication with the access tube and the occluder.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,822,341 to Colone. Colone discloses the apparatus as claimed with the exception of the location of the sealing ports and closed ends of the access tube. It has been held that mere rearrangement of the working parts of a device found in the prior art is obvious to one of ordinary skill in the art. See MPEP 2144.04.

10. Claims 6, 7, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,822,341 to Colone in view of US 4,421,507 to Bokros. Colone discloses the method and device as claimed with the exception of placing the access device in a percutaneous position. Bokros discloses a percutaneous access port with a plug that allows patients to self-administer medications and treatments directly to his or her own vascular system without repeatedly puncturing the skin, which may lead to infection and scarring. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to place the access device disclosed by Colone in a percutaneous

position with a plug in order to allow patient access with minimal scarring and infection, as taught by Bokros.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

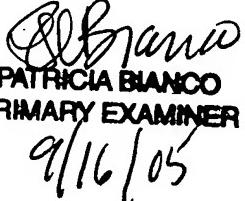
- a. US 5,421,814 Geary et al
 - i. Dialysis access port with occluder
- b. US 5,797,879 DeCampli
 - ii. Adjustable blood flow through a vascular graft

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd 
14 September 2005


PATRICIA BLANCO
PRIMARY EXAMINER
9/16/05